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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,708	07/25/2003	Atsushi Suzuki	240653US0DIV	1894
22850	7590	02/28/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			COE, SUSAN D	
1940 DUKE STREET			ART UNIT	PAPER NUMBER
ALEXANDRIA, VA 22314			1655	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,708

Applicant(s)

SUZUKI ET AL.

Examiner

Susan D. Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,21-23,25,26,28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,20 and 27 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 21, 2005 has been entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

2. Claims 1-5 have been cancelled.

3. Claims 6-9 and 20-29 are pending.

Election/Restrictions

4. In the reply filed on September 13, 2004, applicant elected with traverse of Group II, chlorogenic acid for species A and central nervous system stimulating components for species B. In addition, in the reply filed on June 21, 2005, applicants have elected the species zingerol for the central nervous system stimulating component.

5. Regarding election of species, MPEP section 803.02 states:

... should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species.

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A search of the elected species of zingerol has revealed no prior art. Thus, search has been extended to an additional species, capsaicin. Applicant has requested that all of the heat components from ginger be examined. However, the selection of the next species for examination is under the discretion of the examiner. Capsaicin was selected and the search will not be extended unnecessarily to cover all nonelected species.

6. Claims 8, 9, 21-23, 25, 26, 28, and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 21, 2005 and September 13, 2004.

7. Claims 6, 7, 20, 24, and 27 are examined on the merits in regards to the elected species.

Claim Rejections - 35 USC § 112

8. Claims 6, 7, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the Office action of September 2, 2005.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that "heat component" is definite because "heat" can be measured using the Scoville Scale. However, applicant has not defined what measurements on this scale indicate that a compound is a "heat" component. In addition, the definitions of "heat" components in the specification are not limited but open-ended. Therefore, the metes and bounds of this term are unclear.

Claim Rejections - 35 USC § 103

9. Claims 6, 7, 20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (The Chinese Pharm. Journal (1994), vol. 46, pp. 575-582) and US Pat. No. 6,440,464 for the reasons set forth in the Office action of September 2, 2005.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that Cheng does not teach combining chlorogenic acid with capsiacin. Applicant also argues that US '464 does not teach combining isolated capsaicin with chlorogenic acid. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The references combined are considered to teach a composition of isolated capsaicin and isolated chlorogenic acid to treat hypertension.

Applicant also argues that US '464 does not teach using isolated capsaicin. However, the reference teaches using the chemical form of capsaicin. Thus, the reference teaches using capsaicin that is isolated from its natural source, i.e. peppers. The claimed use of "isolated capsaicin" is not interpreted to leave out any additional ingredients that are added to the capsaicin. "Isolated" is interpreted to exclude a crude extract from a pepper that would contain capsaicin as a natural ingredient. Applicant's claims use "comprising" language which does not exclude unrecited elements. In addition, applicant argues that the reference does not attribute any antihypertensive properties to capsaicin itself. However, since applicant's claims use

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“comprising” the entire composition taught by the reference can be combined with the chlorogenic acid.

In addition, applicant argues that US ‘464 is not an enabling reference because the reference does not show any data to support the use of capsaicin to treat high blood pressure. However, the reference is considered to be enabled. The reference teaches the appropriate dosages of the capsaicin to use to achieve this use. The reference also teaches the specific patient to treat. In addition, blood pressure is easily measured; thus, a person of ordinary skill in the art could easily determine without undue experimentation if the capsaicin composition taught by the reference functions to successfully lower blood pressure. Therefore, the reference is considered to enable the use of capsaicin to lower blood pressure.

Applicant also argues that a person of ordinary skill in the art would not reasonably expect that a combination of chlorogenic acid and capsaicin would function successfully because the capsaicin could potentially negate or inhibit the effect of chlorogenic acid. Specifically, applicant points out that grapefruit juice can be included in the composition of US ‘464. Applicant argues that grapefruit juice is known to inhibit the uptake of numerous types of drugs. However, applicant has provided no specific evidence that would lead a person of ordinary skill in the art to believe that capsaicin or even grapefruit juice would inhibit the hypertensive effects of chlorogenic acid. Applicant’s argument is based on general drug interactions that could reduce a pharmaceutical effect. Without specific teachings in the references that would teach away from combining chlorogenic acid and capsaicin, the teaching of equivalent uses of these ingredients is considered to provide proper motivation and expectation of success for a combination of these ingredients to treat hypertension.

Double Patenting

10. Claims 6, 7, 20, and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/922,694 or Application No. 10/826,289 or Appl. No 10/632,810 or Appl. No 10/810,611 or 11/106,428 in view of US Pat. No. 6,440,464 for the reasons set forth in the Office action of September 2, 2005.

Applicant has requested that this rejection be held in abeyance until allowable subject matter is indicated. For the time being, this rejection is still considered valid for the reasons of record.

Claim Objections/Allowable Subject Matter

11. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information

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about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



2-21-06

Susan D. Coe
Primary Examiner
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